AMENDMENT

Introduction

Claims 26-47 are pending in this application. All claims are currently rejected under 35 U.S.C. 103(a) as being unpatentable over several prior art references.

In the Amendment filed on 27 March 2002, claims were included in two locations in the Amendment. The body of the Amendment contained the language of claims 26 and 36 with bracketed text indicating such text was to be deleted. Appendix A of the Amendment contained a clean version of all claims, however, the bracketed text in claim 36 was not removed from this clean version. This error is corrected in the amended claims presented herewith.

Amendment

Applicant hereby amends Claim 36 as follows:

36. (currently amended – as presented in 27 March 2002 Continued Prosecution Application) A method for delivering the same biologically active material to an animal body in both a rapid release and sustained release form comprising the steps of:

(1) providing an implant comprising:

(a) a first component comprising a biologically active composition contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in an animal body and which is selected from the group consisting of encapsulants where the coating wall material is highly soluble in body fluids, porous or freeze-dried solid compositions, solid tablets or pellets containing a disintegrating agent which causes the solid tablet or pellet to rapidly break down when in body fluids, solid tablets or pellets containing said biologically active material in fine or micronized particle

sizes[, an osmotic delivery system where the osmotic system is such that a substantial amount of the active is released upon implantation] and mixtures thereof; and

(b) a second component comprising the same biologically active composition as in component (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained basis upon implantation in an animal body and which is selected from the group consisting of encapsulated solutions or suspensions, biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, conventional tablets or pellets containing said biologically active material having large particle sizes, matrix-tablets based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix-type systems based on biodegradable polymers, matrix-type systems implant based on lipidic excipients[, mass transfer systems based on osmotic pressure pumping through a hole in an impermeable coating] and mixtures thereof; and

(2) injecting said implant into the animal body.

Remarks

Claims 26 to 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Pat. 5,288,496) in view of Herbert et al. (U.S. Pat. 5,654,008) and Okada et al. (U.S. Pat. 4,652,441). In addition, Stevens et al. (U.S. Pat. 5,874,098), Rickey et al. (U.S. Pat. 5,792,477), and Guittard et al. (U.S. Pat. 4,576,604) have been cited against the instant Application. Applicant respectfully traverses this rejection.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the